

INTERNATIONAL PRELIMINARY EXAMINATION REPORT


(PCT Article 36 and Rule 70)

Rec'd PCT/PTO 03 FEB 2005

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| Applicant's or agent's file reference JAB1709-PCT | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416) | |
| International application No. PCT/EP 03/08696 | International filing date (day/month/year) 05.08.2003 | Priority date (day/month/year) 14.08.2002 |
| International Patent Classification (IPC) or both national classification and IPC A61K31/404 | | |
| Applicant JANSSEN PHARMACEUTICA N.V. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

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|--|--|
| Date of submission of the demand 09.01.2004 | Date of completion of this report 27.08.2004 |
| Name and mailing address of the International preliminary examining authority:  European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840 | Authorized Officer Beyss, E Telephone No. +49 30 25901-344 |



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP 03/08696

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-12 as originally filed

Claims, Numbers

1-12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
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International application No. **PCT/EP 03/08696**

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

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|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-12 |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-12 |
| Industrial applicability (IA) | Yes: Claims | 1-12 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO-A-9312785

D2: US-B1-6365591

1. Clarity

Present claims 1-3, 5, 8-12 relate to a composition containing antagonists and the use of these. No further true technical characteristics of these compounds are given, but rather a definition by reference to a result to be achieved is attempted rendering the scope of said claims unclear (Art. 6 PCT).

2. Novelty

D1 discloses the use of 5-HT₄ receptor agonists for the treatment of conditions associated with bladder hypersensitivity such as urinary incontinence (page 1, line 27-34).

D2 describes the use of alpha-adrenoceptor antagonists like prazosin etc. for the treatment of lower urinary tract symptoms (column 2, line 6-14; column 8, line 21-40).

Present application discloses the use of a pharmaceutical composition containing in admixture alpha-adrenoceptor antagonists and 5-HT₄ receptors agonists for the treatment of lower urinary tract symptoms.

The subject-matter of claims 1-12 of present application is novel over the prior art and hence meets the requirements of Article 33(2) PCT.

3. Inventive Step

D2 is considered to represent the most relevant state of the art. The problem to be

solved by the present invention may therefore be regarded as the provision of a pharmaceutical composition containing smaller amounts of alpha-adrenoceptor antagonists for the treatment of lower urinary tract symptoms.

The solution proposed in claims 1-12 of the present application cannot be considered as involving an inventive step since the feature of the 5-HT₄ receptor agonist is described in the prior art document D1 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the composition described in D2 in order to solve the problem posed.

4. Industrial Applicability

Claims 1-12 meet the requirements of Article 33(4) PCT.